UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHEZAREE BOOKER and QWONJIT NELSON, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

E.T. BROWNE DRUG CO., INC.,

Defendant.

Case No. 7:20-cv-03166 (PMH)

DEFENDANT E.T. BROWNE DRUG CO., INC.'S REPLY IN FURTHER SUPPORT OF ITS MOTION TO DISMISS PLAINTIFFS' CLASS ACTION COMPLAINT

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PRELIMINARY STATEMENT

This Court should grant E.T. Browne's[1] Motion because Plaintiffs' claims contradict the federal law, regulations, and guidance governing the cosmetic claims on E.T. Browne's Products.[2] The Products are labeled and marketed to "help[] reduce the appearance of stretch marks" and moisturize the skin. These claims are consistent with the FDCA's express definition of cosmetics, federal regulations on cosmetics, and FDA guidance providing that moisturizing products are cosmetics. The Opposition attempts to evade the FDCA's preemption clause by arguing that Plaintiffs' claims "impose identical requirements to those imposed by the FDCA." Opp. at 3. Not so: the Complaint and the Opposition contradict federal law by ignoring the critical legal difference between drug claims focusing on preventing or affecting the development of stretch marks and cosmetic claims focusing on improving their appearance. But that difference matters, and preempts Plaintiffs' claims.

To avoid the mismatch between the drug studies on which the Complaint relies and the Products' labels, the Opposition shifts gears and now asserts (contrary to the Complaint) that the Products are "drugs." It does so by mischaracterizing the Products' labels and disregarding the context in which the Products' claims appear. Alternatively, it contends that a "reasonable consumer" might believe that the Products' labels promise to *prevent* stretch marks (a drug claim). Neither gambit works: federal law is clear that the Products' labels make well-recognized cosmetic claims concerning improving the *appearance* of stretch marks by moisturizing the skin. The mismatch between Plaintiffs' drug studies and purported "reasonable

[1] Capitalized terms have the same meaning as in E.T. Browne's Motion to Dismiss Plaintiffs' Class Action Complaint dated September 18, 2020 (the "Opening Brief" or "Op. Br.").
[2] Plaintiffs' Opposition to Defendant's Motion to Dismiss Plaintiffs' Class Action Complaint dated October 16, 2020 at 1 (the "Opposition" or "Opp.") mistakenly states that the Products at issue include "Palmer's Massage Oil," instead of "Massage Cream" as pled in their Complaint.

consumer" understanding, on the one hand, and E.T. Browne's actual Product claims, on the other, viewed in light of governing federal law, shows why Plaintiffs' claims are preempted. And, because the studies do not address the actual Product claims, they also fail to raise a plausible claim that the Products' labels are false or misleading.

Finally, Plaintiffs cannot bring their unjust enrichment claim "in the alternative" as the Opposition contends. Unjust enrichment claims fail where, as here, Plaintiffs have an adequate remedy at law and cannot remedy the defects of their other defective claims. The Complaint should be dismissed, with prejudice.

ARGUMENT

I. PLAINTIFFS' CLAIMS ARE PREEMPTED

The Opposition attempts to evade preemption in three ways. It argues that: (i) the distinction between "cosmetics" and "drugs" does not matter; (ii) the Products are marketed and sold as "drugs"; and (iii) a reasonable consumer would understand the Products to be making drug claims. All three fail.

A. The Difference Between Drugs and Cosmetics Matters: Plaintiffs' State Law Claims are Preempted Because They Would Impose Drug Requirements on Cosmetics

The Opposition asserts that the FDCA's distinction between cosmetics and drugs "[has] no bearing on how consumers, scientists, and the studies" use the terms "treatment" and "appearance." *See* Opp. at 15. That is wrong. The Opposition cites no legal authority for this assertion, and for good reason. Under federal law there is a meaningful difference between treatments claiming to prevent or affect the development of stretch marks and those that help to improve their appearance. *See* Op. Br. at 10–12. This distinction preempts Plaintiffs' claims.

In *Dachauer v. NBTY, Inc.*, 913 F.3d 844 (9th Cir. 2019), the court held that the FDCA preempted plaintiff's claims because the FDCA distinguishes between "structure/ function"

claims (i.e., supporting heart health) and "disease claims" (i.e., preventing heart disease). *Id.* at 848; *see also Kroessler v. CVS Health Corp.*, No. 19-55671, 2020 WL 5987498, at *4 (9th Cir. Oct. 9, 2020) (emphases added) ("[T]he FDCA distinguishes between 'disease claims' and 'structure/function claims' that manufacturers make about their products, *applying different regulatory standards to each*[.]"). As the *Kroessler* Court explained, referring to *Dachauer*:

> Had we permitted the plaintiff's claims to proceed, we would have forced the defendant to substantiate that the supplement also prevented heart disease. That *would have held the defendant to burdens of production and proof different than those required for structure/function claims under the FDCA.* Therefore, the FDCA preempted the plaintiff's claim.

Kroessler, 2020 WL 5987498, at *6 (emphases added). That *Dachauer* and *Kroessler* involved supplements (as opposed to cosmetics) is beside the point, and does not lessen their import. The preemptive principle under the FDCA that there cannot be a mismatch between federal law and the purported support for state law claims applies equally to both supplements and cosmetics. Just as it distinguishes between drugs and supplements, the FDCA distinguishes between drugs and cosmetics and applies different regulatory standards to each.

The Second Circuit has recently described the FDCA's preemption clause for the labeling or packaging of cosmetics as "broad." *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 38 (2d Cir. 2020) (discussing "Congress's broad, categorical statement of preemption in the FDCA" for cosmetic products); *see* 21 U.S.C. § 379s. In *Critcher*, the Second Circuit affirmed the district court's preemption finding where, in order to avoid liability under plaintiffs' theory, defendant would have had to make a disclosure on its cosmetic packaging that was different from and in addition to the FDCA's requirements. *Critcher*, 959 F.3d at 36. Here, E.T. Browne's Products' labeling is consistent with the FDCA's definition of cosmetics and FDA guidance stating that "[i]f cosmetic claims, e.g., moisturizing . . . skin softening, etc. are made on a label, *the product*

is a cosmetic." *Cosmetics Labeling Guide*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide (current as of Aug. 24, 2020) ("FDA: Cosmetics Labeling Guide") (emphasis added). Were Plaintiffs' claims to proceed, E.T. Browne would be held to burdens applicable to drug claims, which differ from those required for cosmetic claims under the FDCA. Because Plaintiffs' state law claims contradict federal law in this way, they are preempted.

B. The Products are Cosmetics Under Federal Law

To avoid preemption, the Opposition mischaracterizes the Products' labels and contends (contrary to the Complaint and federal law) that the Products are drugs, not cosmetics. Opp. at 5. This argument is meritless.[3]

The Complaint nowhere alleges that the Products are drugs, nor can it. *See e.g.*, Compl. ¶ 55 (emphasis added) ("Defendant is a top distributor of *cosmetic* products in the United States."); *see also id.* ¶ 9 (purporting to rely on studies related to "topical cosmetics"). Nonetheless, the Opposition shifts gears and contends that the Products are drugs instead of cosmetics. Opp. at 5. Plaintiffs, however, are "not permitted to interpose new factual allegations or a new legal theory in opposing a motion to dismiss, let alone new allegations that contradict the allegations in their pleading." *Uddoh v. United Healthcare*, 254 F. Supp. 3d 424, 429 (E.D.N.Y. 2017); *see also K.D. ex rel. Duncan v. White Plains Sch. Dist.*, 921 F. Supp. 2d 197, 209 n.8 (S.D.N.Y. 2013) ("Plaintiffs cannot amend their complaint by asserting new facts or theories for the first time in opposition to Defendants' motion to dismiss.").

[3] Contrary to the Opposition (Opp. at 10–11), to the extent Plaintiffs contend that the Products make unauthorized drug claims, their N.Y. G.B.L. § 349 claim would be predicated on a violation of the FDCA. *See Verzani v. Costco Wholesale Corp.*, No. 09 CIV 2117, 2010 WL 3911499, at *3 (S.D.N.Y. Sept. 28, 2010), *aff'd*, 432 F. App'x 29 (2d Cir. 2011).

But even if the Court were to consider it, the Opposition's new "drug" claim fails because it mischaracterizes the Products' labels. For example, the Opposition takes the Tummy Butter's "intensive treatment" label out of context by ignoring that it appears directly beneath the words "helps reduce the *appearance* of stretch marks." RJN, Ex. C (emphasis added);[4] *see Fink v. Time Warner Cable*, 714 F.3d 739, 742 (2d Cir. 2013) ("[I]n determining whether a reasonable consumer would have been misled by a particular advertisement, context is crucial."). In fact, the FDA specifies that products such as "wrinkle *treatments*" are cosmetics where, as are the E.T. Browne Products, they are "intended to make lines and wrinkles less noticeable, simply by moisturizing the skin." *Wrinkle Treatments and Other Anti-aging Products*, U.S. FOOD & DRUG ADMINISTRATION, https://www.fda.gov/cosmetics/cosmetic-products/wrinkle-treatments-and-other-anti-aging-products (current as of Sept. 11, 2020) ("FDA: Wrinkle Treatments"); *id.* (emphases added) (in contrast to products that, for example, claim "to *remove* wrinkles or *increase the skin's production* of collagen"). The Opposition also asserts that the Products' labels claim to "allow 'skin to stretch more easily,' *so new stretch marks will not form*" (Opp. at 1 (emphases added) (citing RJN, Ex. A)), but the actual labels do not state anywhere that they will prevent stretch marks from forming (*see* RJN, Ex. A). The Opposition just makes that up. Nor do the Product instructions limit product application to specific areas (Opp. at 5–6), but instead instruct consumers to "*[a]pply all over skin*" (RJN, Ex. A (emphases added)), which is consistent with the Products' use as cosmetic moisturizers. As shown in the Opening Brief, the

[4] Nor is it proper to pretend that the words on one Product's labels appear on the other two. *See* Opp. at 16 (contending that the Massage Lotion and Cream are "treatments" when neither label uses the term). What matters are the words that appear on each Product's actual label. *See e.g.*, *Bowring v. Sapporo U.S.A., Inc.*, 234 F. Supp. 3d 386, 389 (E.D.N.Y. 2017) (evaluating complete labels for each variety of beer).

Products—a massage cream, lotion, and body butter—are cosmetics as a matter of law. Op. Br. I.A.

C. Plaintiffs Cannot Evade Preemption By Invoking a "Reasonable Consumer" Understanding That Conflicts With Federal Law

The Opposition also contends that Plaintiffs' claims are not preempted because "the FDCA does not regulate whether claims are misleading" and because a reasonable consumer might read the Products' labels as promising to *prevent* and treat the *development* of stretch marks (a drug claim) as opposed to helping reduce their appearance. Opp. at 4–7, 13. It is wrong for at least two reasons.

First, the very purpose of the FDCA is "to protect consumers from fraud or misrepresentation in the sale of food, drugs, and cosmetics." *O'Connor v. Henkel Corp.*, No. 14-CV-5547, 2015 WL 5922183, at *3 (E.D.N.Y. Sept. 22, 2015). The FDA is the agency charged with ensuring that "cosmetics are safe and properly labeled." *Id.* (citing 21 U.S.C. § 393(b)(2)(D)). And, as shown in the Opening Brief, the FDA has done so by promulgating regulations and guidance that make clear that products labeled to affect the appearance of the skin by moisturizing are cosmetics, not drugs. Op. Br. I.A.

Second, because the Products' labels comply with federal law and guidance, this Court can decide, as a matter of law, that no reasonable consumer would be misled by them. *See Fink*, 714 F.3d at 741 ("It is well settled that a court may determine as a matter of law that an allegedly deceptive advertisement would not have misled a reasonable consumer."). This is particularly true when the supposed "reasonable consumer" reading contradicts federal law and FDA guidance. The "reasonable consumer" standard applies only where federal law and regulations do not address the subject matter of state law claims. *See e.g.*, *Bimont v. Unilever U.S., Inc.*, No. 14-CV-7749, 2015 WL 5256988, at *1 (S.D.N.Y. Sept. 9, 2015) (dismissing state law claims as

preempted because federal law governed the subject matter of the state law claims, despite plaintiffs' contention that packaging misled them "and other reasonable consumers").

And here, federal law specifically addresses the subject matter of Plaintiffs' state law claims. *See* 21 U.S.C. § 321(i); 21 C.F.R. § 720.4(c)(12); FDA: Wrinkle Treatments; FDA: Cosmetics Labeling Guide. This is in stark contrast to the cases the Opposition cites. *See e.g.*, *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 320–21 (S.D.N.Y. 2017) (none of the "federal requirements" that defendants relied upon addressed the subject matter of plaintiff's state law claims); *Reid v. GMC Skin Care USA Inc.*, No. 815CV277, 2016 WL 403497, at *10 (N.D.N.Y. Jan. 15, 2016) (defendant could not explain how plaintiffs' interpretation of California and Washington state laws impermissibly expanded on the federal standards); *Elkind v. Revlon Consumer Prod. Corp.*, No. 14-CV-2484, 2015 WL 2344134, at *8 (E.D.N.Y. May 14, 2015) (emphases added) (finding no preemption due to "lack of any suggestion that the FDA is at all interested in issuing any relevant guidance" and reasoning that "[t]hose cases that have found similar state-law claims pre-empted have done so *where the FDA has spoken on a certain practice* . . . ."). As one of Plaintiffs' cases explains, preemption does not apply where claims "*do not require reference to FDA definitions* and the misleading nature of the statement [could] be verified without relying on any special expertise of the FDA." *Jovel v. i-Health, Inc.*, No. 12-CV-5614, 2013 WL 5437065, at *5 (E.D.N.Y. Sept. 27, 2013) (emphases added). But that is not remotely the case here. Plaintiffs' claims implicate and contradict the FDA's definition of, and guidance on, cosmetics and are accordingly preempted. Op. Br. at 12–13; *see Critcher*, 959 F.3d at 38 ("21 U.S.C. § 379s [] bars Plaintiffs from seeking to impose additional or different labeling requirements through their state-law claims, especially when Congress and the FDA already have provided for specific labeling requirements.").

Plaintiffs' claims should accordingly be dismissed as preempted.

II. PLAINTIFFS FAIL TO STATE A CLAIM BECAUSE THEIR STUDIES DO NOT SHOW THAT THE PRODUCTS CANNOT HELP REDUCE THE APPEARANCE OF STRETCH MARKS

As shown in the Opening Brief and Request for Judicial Notice, none of Plaintiffs six studies analyzed the Products' cosmetic claims that they "help[] reduce the appearance of stretch marks." The Ud-Din Article considered the "*prevention* of [stretch marks]." RJN, Ex. D at 220. The Osman Study "assess[ed] whether application of cocoa butter lotion *reduces the development*" of stretch marks. RJN, Ex. E at 1138 (emphases added). The Buchanan Study similarly studied whether cocoa butter was "effective in *preventing*" stretch marks as compared to application of a placebo. RJN, Ex. F at 65 (emphasis added). The Brennan Study analyzed the *development* of stretch marks and the Hague Review evaluated the "*development of new*" stretch marks. RJN, Ex. G at 1, Ex. H at 568e17 (emphases added). None of the studies evaluated the Products' claims that they improve the appearance of the skin by moisturizing—claims which, as discussed, the FDA considers permissible cosmetic claims. As in *Kardovich*, because the studies do not evaluate the Products' claims, "the science does not undercut" them. *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131, 138 (E.D.N.Y. 2015).[5] Plaintiffs therefore have not raised a plausible claim that E.T. Browne's labels are false, deceptive, or misleading.

[5] The Opposition contends that an "evidentiary analysis" is not appropriate on a motion to dismiss. Opp. at 8. However, courts routinely review the contents of studies on motions to dismiss, not to weigh evidence, but to determine whether the allegations of complaints are plausible. *See e.g.*, *Sabol v. Bayer Healthcare Pharm., Inc.*, 439 F. Supp. 3d 131, 148 (S.D.N.Y. 2020) (citation omitted) ("[W]here scientific studies are cited and thus incorporated into the complaint, and where those studies simply do not support the allegations, the Court may find that the deficiencies . . . go to the very heart of the plausibility standard under *Iqbal*."); *Kardovich*, 97 F. Supp. 3d at 138 (analyzing fundamental mismatch between plaintiffs' studies and defendant's challenged statements); *see also Tubbs v. AdvoCare Int'l, L.P.*, 785 F. App'x 396, 397 (9th Cir. 2019); *Eckler v. Wal-Mart Stores, Inc.*, No. 12-CV-727, 2012 WL 5382218, at *7 (S.D. Cal. Nov. 1, 2012). This Court should also.

Finally, the Moore Article, which notes that the American Academy of Dermatology ("AAD") has stated that "a moisturizer can improve the appearance of stretch marks " (RJN, Ex. I at 758), contradicts Plaintiffs' claims and thus supports their dismissal. Op. Br. at 21; *see also Alamilla v. Hain Celestial Grp., Inc.*, 30 F. Supp. 3d 943, 944 (N.D. Cal. 2014) (dismissing complaint with prejudice because "[t]he articles the plaintiffs cite . . . contradict the allegation upon which their entire complaint hinges"). Not surprisingly, the Opposition now retreats from Moore, suggesting the Court should disregard that section of the Article that quotes the AAD, purportedly because the AAD's current website "does not discuss moisturizers and makes no such recommendation." Opp. at 19. Not so. Referring to "creams, lotions, and gels," the AAD's current website states that "[t]aking time to massage the product gently into your skin may make it more effective." *See Stretch Marks: Why They Appear and How to Get Rid of Them*, AAD, https://www.aad.org/public/cosmetic/scars-stretch-marks/stretch-marks-why-appear (last visited Oct. 30, 2020). Because the Moore Article and AAD website it quotes both contradict Plaintiffs' claims, they should be dismissed.

III. PLAINTIFFS' UNJUST ENRICHMENT CLAIM FAILS

The Opposition nowhere explains why Plaintiffs' equitable claim for unjust enrichment should survive when Plaintiffs plainly have adequate remedies at law, namely their claims for violation of New York GBL §§ 349 and 350, breach of express warranty, and fraud. Op. Br. at 23; *see also Samiento v. World Yacht Inc.*, 10 N.Y.3d 70, 81 (2008) ("unjust enrichment . . . does not lie as plaintiffs have an adequate remedy at law"). For this reason alone, it should be dismissed. And even if, as the Opposition contends, the unjust enrichment claim could be pled in the alterative, it fails where it cannot remedy the defects in their other claims, which are preempted and fail to state a plausible claim. *See Gonzalez v. Costco Wholesale Corp.*, No. 16-

CV-2590, 2018 WL 4783962, at *11 (E.D.N.Y. Sept. 29, 2018). Accordingly, the unjust enrichment claim should be dismissed.

CONCLUSION

Defendant E.T. Browne respectfully requests that the Court grant its Motion and dismiss the Complaint in its entirety, with prejudice.

Dated: Petaluma, California
October 30, 2020

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